Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program Fiscal Year 2007

Presented by
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Introduction

- CDMRP overview
- PTSD/TBI* Research Program overview
- Investment strategy
- PTSD/TBI Research Program Award mechanisms
- Outcomes of Programmatic Review

*Former name of the Program

CDMRP History

- In 1993, grassroots advocacy heightened political awareness of breast cancer
- Federal budgetary opportunities spurred Congress to appropriate $210M to the DOD budget for the Breast Cancer Research Program
- Program assigned to the USAMRMC; subsequent consultation with the Institute of Medicine (IOM) for programmatic advice
- Additional research programs added and managed by the CDMRP

Partnerships

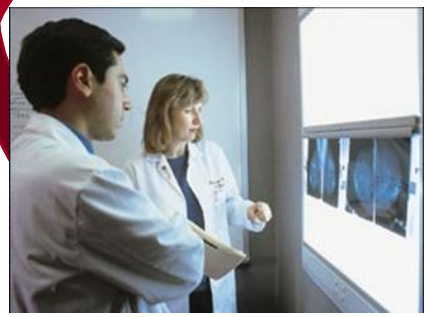
Advocates

- Demonstrate need
- Participate at all levels
- Passion and perspective

Researchers

- Innovation and gaps
- Risk/Benefit
- Product-oriented

IMPROVE HEALTH (CURE)



Congress

- Add funds to budget
- Targeted guidance
- Opportunity to leverage

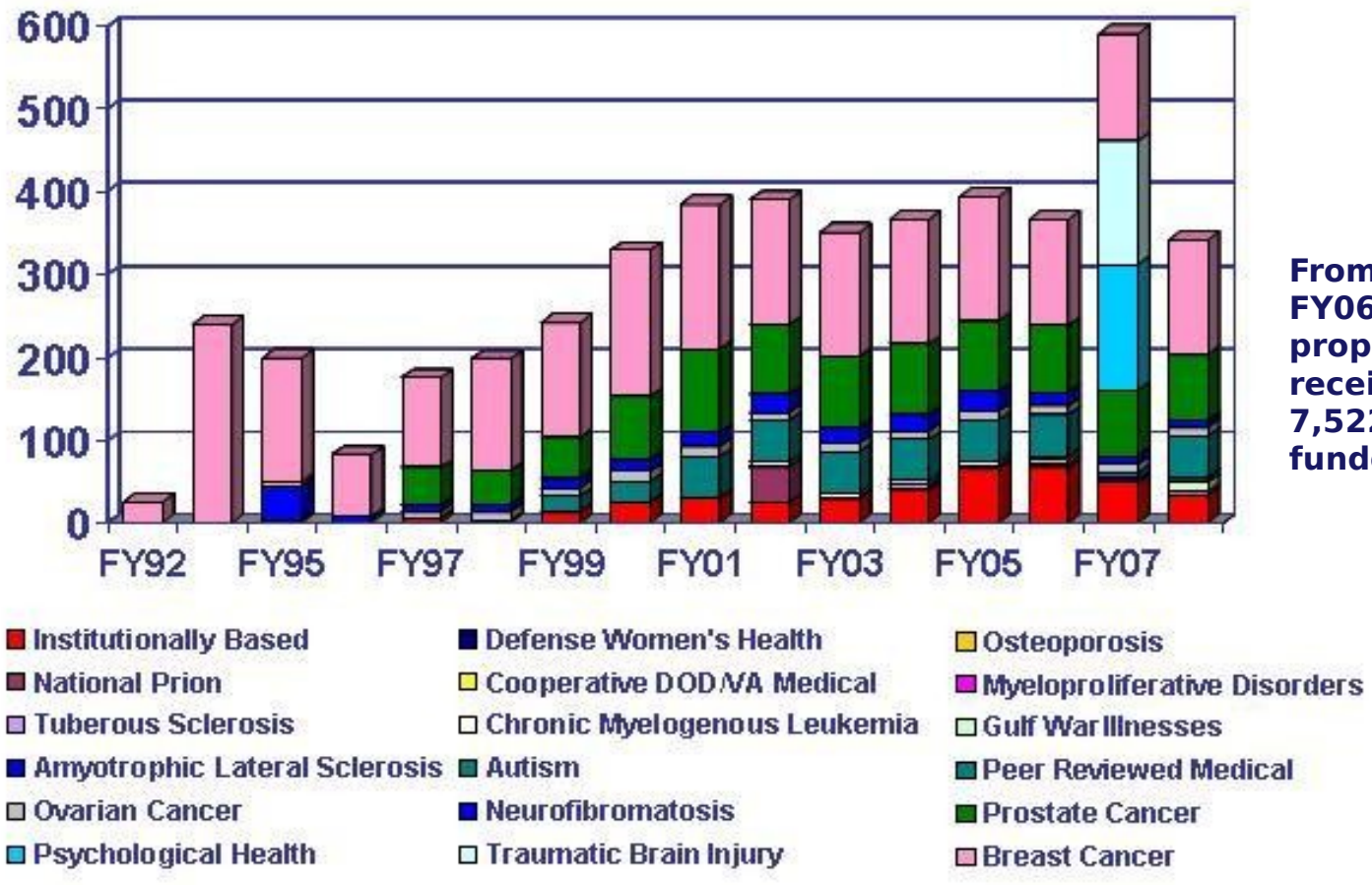
DOD

- Program management
- Regulatory/ budget requirements
- IOM model

Program Features

- Directed by Congress
- Targeted research
- Two-tier formal review of proposals – Institute of Medicine model
- Responsive management
- Consumer participation

CDMRP Funding History



From FY02-FY06 44,923 proposals received and 7,522 awards funded

Congressional Language

FY07 PTSD, TBI, Burn Orthopedic and Trauma Supplemental Funding:

The "U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act," Public Law 110-28, appropriated $331,700,00 to the Defense Health Program account for research, development, test, and evaluation to remain available until September 30, 2008. Consistent with Congressional intent, as established by related Conference Committee report, these funds are allocated for peer reviewed research as follows: $150,000,000 for PTSD research; $150,000,000 for TBI research; and $31,700,000 for BOT research.

Background

- **Stakeholders Meetings**
  - **11-12 June 2007**
  - **Purpose: Discuss state of the science and research gaps**
  - **Participants: Army, Navy, Air Force, Marine Corps, OSD(HA)*, Veterans Affairs, NIH, Private Industry, and Academia**
- **Vision Setting Meeting: 13 June 2007**
  - **Conducted by the Joint Program Integration Panel (JPIP)**
  - **Established program vision**
  - **Prioritized research gaps**
  - **Established investment strategy**

***OSD(HA): Office of the Assistant Secretary of Defense for Health Affairs**

FY07 Joint Program Integration Panel (JPIP)

Chair
COL Karl Friedl

Alternate Chair
Mr. Michael Leggieri

DCoE* Director
BG Loree Sutton

Alternate to DCoE Director
CDR Russell Shilling

ASBREM† Secretariat Members

Army:
COL R. Keith Martin

Navy:
CAPT Doug Forcino

Air Force:
Dr. Garrett Polhamus

DDR&E:
Mr. Bart Kuhn

OSD(HA):
Dr. Sal Cirone

Interagency

VA:
Dr. Joseph Francis

NIH:
Dr. Walter Koroshetz

Medical Materiel Developer
Dr. Keith Prusaczyk

Other DoD Representatives
COL Jonathan Jaffin (Army)
COL Tony Carter OSD(HA)
Col Robert Ireland OSD(HA)
Dr. Steve Kaminsky (USUHS**)
Dr. James Wargo (JIEDDO‡)

Service Clinical Consultants

Air Force:
LtCol Debra Malone
Col Michael Jaffee
Maj William Isler

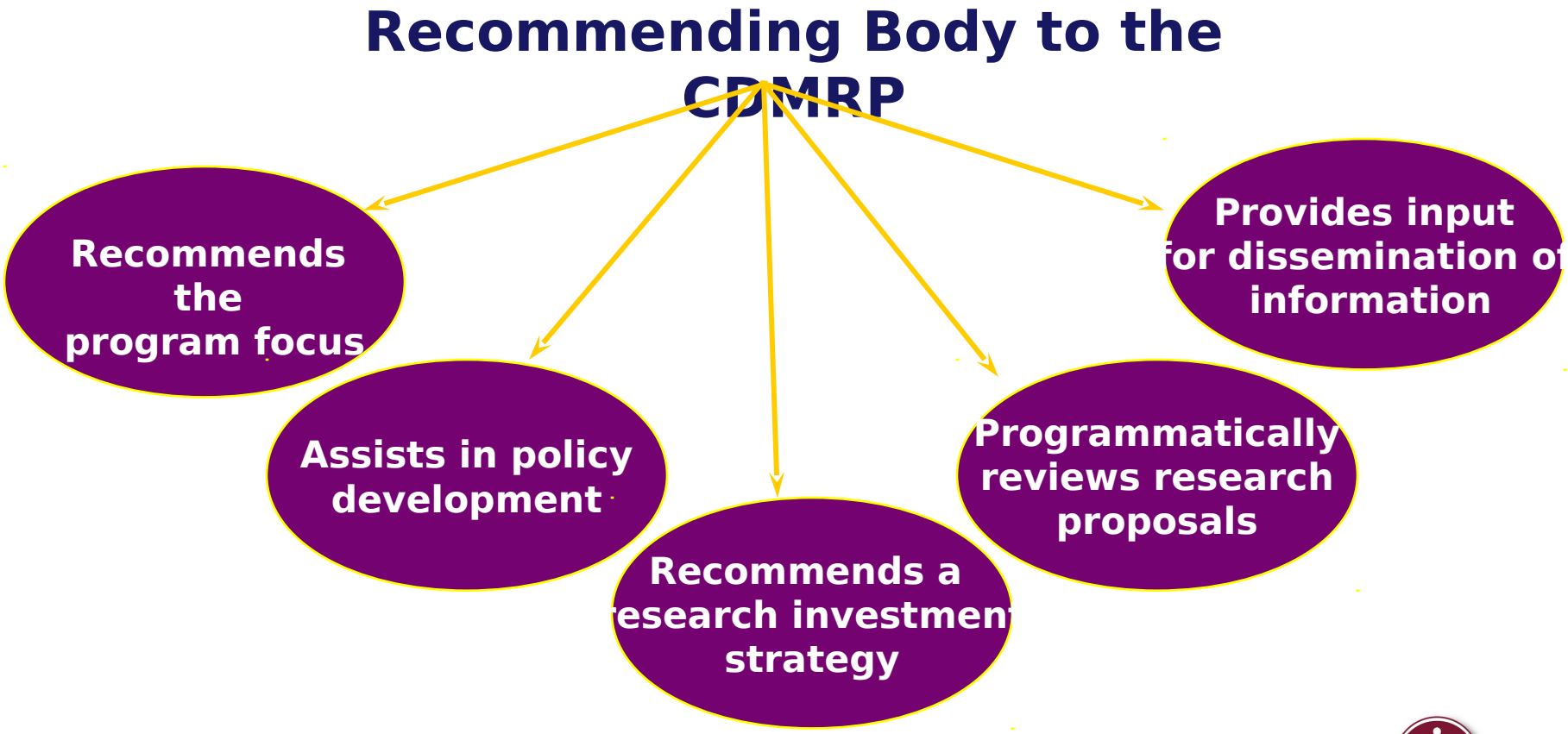
Army:
COL Mary Erickson
COL Elspeth Ritchie
LTC Kurt Grathwohl

Marine Corps:
CDR William Tanner
Mr. Bruce Barnes

Navy:
CAPT Robert Koffman
CAPT James Bloom

*Defense Center of Excellence
†Armed Services Biomedical Research Evaluation Management
**Uniformed Services University of the Health Sciences
‡Joint Improvised Explosive Device Defeat Organization

Integration Panel (IP)


Recommending Body to the CDMRP
Recommends the program focus
Assists in policy development
Recommends a research investment strategy
Programmatically reviews research proposals
Provides input for dissemination of information

Vision and Mission

VISION: To prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service members as well as their caregivers and families

MISSION: Establish, fund, and integrate both individual and multi-agency research efforts that will lead to improved prevention, detection, diagnosis, and treatment of post-traumatic stress disorder and traumatic brain injury

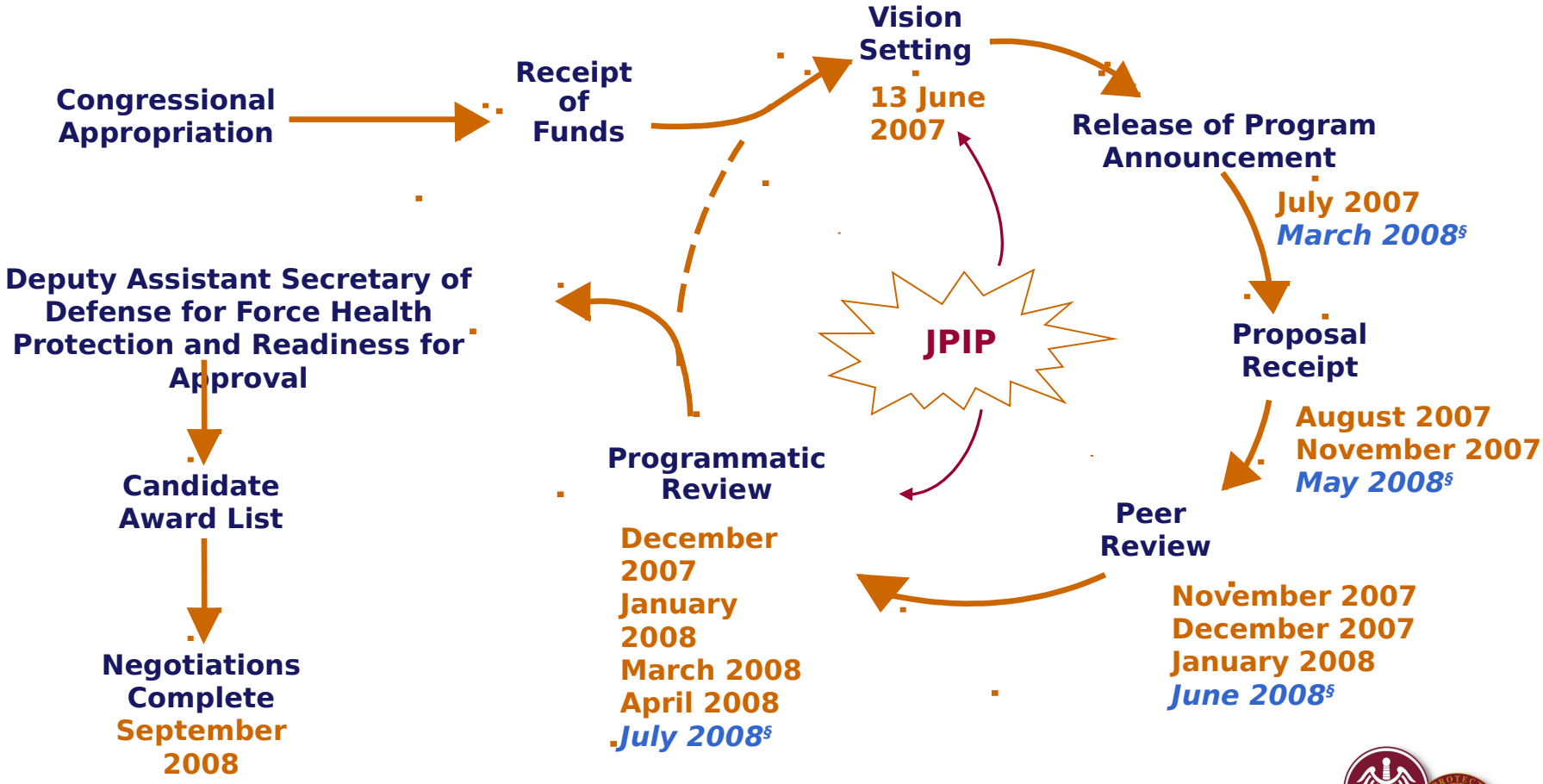
Prioritized TBI Research Gaps and Percent of Funds Allocated

- Treatment and Clinical Management: 40%
- Neuroprotection and Repair Strategy: 22.5%
- Rehabilitation/Reintegration Strategies: 15%
- Field Epidemiology: 15%
- Physics of Blast as It Relates to Brain Injury: 7.5%

Prioritized PTSD Research Gaps and Percent of Funds Allocated

- **Treatment and Intervention: 50%**
- **Prevention: 15%**
- **Measures in Screening, Detection, and Diagnosis: 10%**
- **Epidemiological Studies: 10%**
- **Families/Caregivers Projects: 10%**
- **Neurobiology/Genetics: 5%**

Program Cycle



§Complementary and Alternative Medicine Research Program

FY07 PTSD/TBI Award Mechanisms

Mechanism: Maximum Direct Costs	Key Initiative
Intramural Investigator-Initiated Research: $600K/4years	To accelerate ongoing basic and clinically oriented DOD and VA research that supports (1) substantial improvements over today's approach to the treatment and clinical management of PTSD and/or TBI, (2) the development of novel preventive measures, and (3) the implementation of processes and procedures to enhance the quality of life of persons with PTSD and/or TBI
Intramural Advanced Technology – Therapeutic Development: $4M/4 years	To accelerate the introduction of improved therapies, treatments, devices, or technologies for PTSD and/or TBI into the clinical setting
Concept Award: $150K/18 months	To spark new ideas, innovative technologies, and groundbreaking concepts that will drive the field of PTSD and/or TBI research forward
New Investigator: $300K/3 years	To increase the number of established PTSD and/or TBI researchers

FY07 PTSD/TBI Award Mechanisms (Continued)

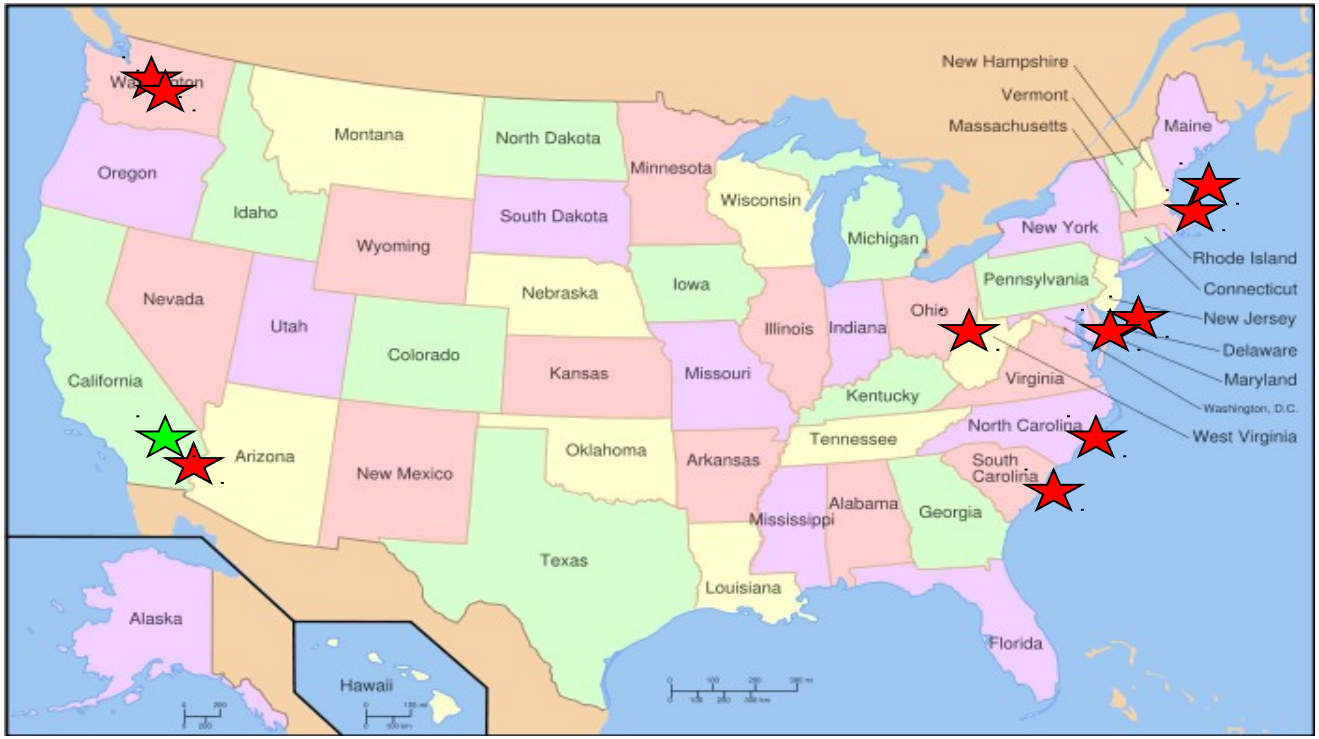
Mechanism: Maximum Direct Costs	Key Initiative
Investigator-Initiated Research: $600K/4 years	To support basic and clinically oriented research that will (1) result in substantial improvements over today's approach to the treatment and clinical management of PTSD and/or TBI, (2) facilitate the development of novel preventive measures, and (3) enhance the quality of life of persons with PTSD issues and/or TBI
Advanced Technology – Therapeutic Development: $4M/4years	To assess therapeutics and devices for the treatment, prevention, detection, and diagnosis for PTSD and/or TBI
Multidisciplinary Research Consortium: $25M/5years	To optimize research and accelerate the solution of a single critical major overarching problem in PTSD and/or TBI research relevant to the prevention, detection, diagnosis, and/or treatment of PH issues and/or TBI
PTSD/TBI Clinical Consortium: $60M/5 years (total costs)	To escalate development and marketing of novel, military-relevant PTSD and TBI treatments and interventions

PH/TBI Research Program Investment by Research Gaps to Date

PTSD Research Gaps	Funded/Received	Budget*	% Invested	% Recommended by JPIP
Treatment and Intervention	41/225	$99.5M	74.0	50
Prevention	7/37	$4.2M	3.1	15
Screening, Detection, and Diagnosis	4/93	$3.4M	2.5	10
Epidemiological Studies	8/54	$4.2M	3.1	10
Families/Caregivers	5/29	$2.9M	2.1	10
Neurobiology/Genetics	19/180	$10.1M	7.5	5
TBI Research Gaps	**Funded/Received**	**Budget**	**% Invested**	**% Recommended by JPIP**
Treatment and Clinical Management	26/305	$92.8M	69.0	40
Neuroprotection and Repair Strategies	20/432	$20.5M	15.2	22.5
Rehabilitation/Reintegration Strategies	8/145	$6.2M	4.6	15
Field Epidemiology	8/66	$3.5M	2.6	15
Physics of Blast	12/73	$7.5M	5.6	7.5

*The Epidemiology the Clinical Consortium Coordinating Center and Study Sites was distributed between both PH and TBI gaps

Locations of Clinical Consortium Coordinating Center and Study Sites



Coordinating Center Study Sites

Coordinating Center:

UCSD

Study Sites:

- Dartmouth College
- Duke University
- Madigan Army Medical Center
- Medical University of South Carolina
- Spaulding Rehabilitation Hospital
- USUHS
- UCSD
- University of Cincinnati
- University of Maryland
- University of Washington

Military and VA Collaborations

Number of Collaborations by Institution Type				
	Military	VA	Academia	Business/ Foundations
Military	N/A	4	26	1
VA	4	N/A	16	2

PTSD Clinical Trials Recommended for Funding

- **29 trials; total cost: ~$58M**

Treatment

- **Neurobiology of Sleep and Sleep Treatments in PTSD (NOS-STIP)**
- **Using Propranolol to Block Memory Reconsolidation in Female Veterans with PTSD**
- **Randomized Controlled Equivalence Trial Comparing Videoconference and Face-to-Face Delivery of Cognitive Processing Therapy for PTSD**
- **Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the Treatment of Soldiers with PTSD**
- **Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women**
- **Telemedicine for Improved Delivery of Psychosocial Treatments for Post-Traumatic Stress Disorder**
- **Telemental Health and Cognitive Processing Therapy for Rural Combat Veterans with PTSD**
- **A Randomized, Placebo-Controlled Trial of the Dopamine Beta Hydroxylase (DBH) Inhibitor, Nepicastat, for the Treatment of PTSD in OIF/OEF Veterans**
- **Neural Correlates of Early Intervention for PTSD**
- **Prazosin for Treatment of Patients With PTSD and Comorbid Alcohol Dependence**
- **A Placebo-Controlled Augmentation Trial of Prazosin for Combat Trauma PTSD**
- **The STRONG STAR Multidisciplinary PTSD Research Consortium (several clinical trials proposed)**

PTSD Clinical Trials Recommended for Funding (continued)

Cognitive Behavioral Therapy

- Cognitive Behavioral Social Rhythm Therapy (CBSRT) for Sleep and Mood Disturbances in Veterans with PTSD
- Pilot Trial of Inpatient Cognitive Therapy for the Prevention of Suicide in Military Personnel With Acute Stress Disorder or Posttraumatic Stress Disorder
- Effectiveness of Cognitive Exposure and Skills Group Manualized Treatments in OIF/OEF Female Veterans
- CBT for Nightmares in OEF/OIF Veterans
- PTSD-Focused Cognitive Behavioral Therapy for Partner Violent OIF/OEF Veterans

Intervention

- Family-Based Intervention with Traumatized Service Members and Their Young Children
- Identification of and At-Risk Interventions for Predeployment Psychophysiologic Predictors of Postdeployment Mental Health Outcomes
- Homecoming Line: Telephone Support for Veterans
- Soldier to Civilian: RCT of an Intervention to Promote Postdeployment Reintegration

Quality of Life

- The Impact of Supported Employment Versus Standard Vocational Rehabilitation in Veterans with PTSD

TBI Clinical Trials Recommended for Funding

- 9 clinical trials; total cost:~$27M

Treatment

- Treatment of TBI Using NNZ-2566: Clinical Trials
- A Randomized Controlled Trial of Medical Therapies for Chronic Post-Traumatic Headaches
- Mission Connect Mild TBI Translational Research Consortium
- Clinical Phase II-B Trial of Oxycyte Perfluorocarbon in Severe Human TBI
- A Double Blind Trial of Divalproex Sodium for Affective Liability and Alcohol Use Following TBI

Intervention

- Telerehabilitation for OIF/OEF Returnees with Combat-Related TBI
- Improving Work Outcomes for Veterans with TBI
- Multi-Family Group Intervention for OEF/OIF TBI Survivors and their Families
- Translation of Cognitive Neuroscience to Rehabilitation for Patients with TBI

http://cdmrp.army.mil